July 19, 1999

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Food & Drug Admin.;
RE: Docket No. 98N-1265:

I am writing about the FDA Modernization Act of 1997, Section 503A, which has to do with interstate shipping of compounded prescriptions. In 1984 at age 36, I had a total hysterectomy. For one year I was on Premarin 1.25. Because of drastic night sweats, a year later my Doctor added a monthly shot of Depotestadiol. For 15 years I have taken Premarin, fourteen years getting a monthly shot to help control the night sweats. I am not talking about hot flashes, but about drenching sweats that totally disrupted the sleep of both myself and husband. Three weeks after the shot, the sweats would build up until I could get another shot to carry me through another 4 weeks, until I could get another. Working with my Dr., we tried various different hormone therapies on the market, always going back to Premarin and the shot as most effective. These were all manufactured therapies and drugs. Two months ago after researching hormone therapy, I found the Women's Institute Pharmacy located in Wisconsin. For 2 months I have been on a natural hormone prescription developed to control my particular symtoms. I am in contact with the pharmacy monthly, and can have my Dr. change the prescription according to symptoms as they occur. It is a triangle between myself, the Dr. and Pharmacy, something a regular pharmacy has never done. I want to make it plain that I did not go this route because it is a natural program but because I could no longer live with the side effects of the medicine I was on. The bonus for me is that it is really working for me so far. Even the normal hot flashes have abated, and without the monthly jab in the behind. So why am I so unhappy and upset? I live in Minnesota, the pharmacy is in Wisconsin. I understand the MOU will restrict my access to this compounded drug. After 15 years of taking medication that was not totally effective, it is insane that now that I have finally found something that works, it will become unavailable through FDA rules and regulations. In its present form, the Mou, as well as the Compounding Section 503A of the modernization Act, severely restricts the rights of physicians and patients to obtain health care products from the provider of their choice, and infringes on the rights of compounding pharmacists to serve the public's medical needs. Since this is an FDA approved prescription, I feel this regulation is infringing on my right to needed medication.

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Dockets Management Branch (HFA-305)
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